

REMARKS

This amendment is responsive to the Office Action dated August 5, 2003. Applicant has added claims 27 and 28, and amended claims 12 and 22. Claims 1-28 are pending.

Restriction Under 35 U.S.C. § 101

The Examiner rejected claims 12-20 under 35 U.S.C. § 101, asserting that the claimed invention is directed to non-statutory subject matter. The Examiner recommended that the phrase in claim 12 “device that contacts an organ” be changed to “device that is adapted to contact an organ.” The Examiner further recommended that the phrase in claim 12 “device that extends around a substantial volume of the organ” be changed to “device that is adapted to extend around a substantial volume of the organ.”

Applicant traverses the rejection under section 101. Without agreeing that such changes are required to avoid a section 101 problem, however, Applicant has made the recommended amendments to claim 12. Accordingly, Applicant requests that the Examiner withdraw the rejection under section 101.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claim 22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner pointed out that the “wherein adhering” phrase lacked an antecedent basis. Applicant has amended claim 22 to address this concern, and Applicant submits that claim 22, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-4, 12, 14, 17-19 and 21-24 under 35 U.S.C. § 102(b) as being anticipated by Anstadt (US 5,119,804). According to the Examiner, Anstadt teaches an apparatus comprising a manipulating device that is adapted to contact an organ, a bag-like device that is adapted to extend around a substantial volume of the organ and the manipulating device. The Examiner further asserted that the bag-like device is formed of a flexible polymer, further comprising a center region that engages the manipulating device, and a

support shaft, which is a vacuum tube, coupled to the manipulating device. In addition, the Examiner stated that Anstadt teaches a method comprising engaging a manipulating device with the apex of the heart to define a chamber, applying vacuum pressure to the chamber such that a portion of the manipulating device deforms to substantially seal the chamber against leakage, deploying a bag-like device around at least a portion of the heart, and manipulating, supporting or securing the heart with the bag-like device.

Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the amended claims. In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must expressly or inherently describe each and every limitation set forth in a patent claim. Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002); Lewmar Marine, Inc. v. Barient, Inc., 3 USPQ2d 1766, 1767 (Fed. Cir. 1987). This well-known rule of law is commonly referred to as the “all-elements rule.” As demonstrated below, Anstadt fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Claims 1-4, 12, 14, 17-19 and 21-24

Independent claims 1, 12 and 21 recite a “bag-like device.” Independent claims 1 and 21 recite “deploying a bag-like device around” at least a portion of a heart or around a substantial volume of an organ. Independent claim 12, as amended, recites “a bag-like device that is adapted to extend around a substantial volume” of an organ. The Examiner apparently concluded that “bag-like device” reads on liner 50 as described in Anstadt.

The Anstadt liner is not a bag-like device. Rather, liner 50 forms an annular diaphragm 56. Column 5, line 15. In particular, liner 50 includes an upper end 52 and a lower end 54, with large openings at both ends. Further, liner 50 is bonded to cup-shaped member 30 at both upper end 52 and a lower end 54. Column 5, lines 6-12 and 24-27. Rather than being bag-like, liner 50 is annular or tube-like. Liner 50 forms a flexible, inflatable sidewall with only the middle part of liner 50 being free to move. Column 5, lines 13-16.

Contrary to the Examiner’s assertion, element 70 in Anstadt does not represent a “center region that engages the manipulating device,” as recited in claim 14, or a “center region” as recited in claim 16. Rather, element 70 represents an air inlet, and is located at the apical end of

cup-shaped member 30. Column 5, lines 46-50. Accordingly, element 70 is not a center region of any bag-like device. Furthermore, the description of Anstadt liner 50 being open at upper end 52, and specifically the description of Anstadt liner 50 being open proximate to air inlet 70, means that liner 50 could not have a “center region” as recited in claims 14 and 16.

Moreover, Anstadt fails to provide any teaching that would have suggested the desirability of modification to include a bag-like feature instead of an annular diaphragm. On the contrary, Anstadt suggests that liner 50 must be annular, with large openings at both ends and with both ends bound to cup-shaped member 30. The annular nature of liner 50 is central to its function, as positive and negative air pressures applied via inlet 60 to adjust the pressure between liner 50 and cup 30 to provide cardiac massage. Column 5, lines 30-34; FIGS. 5, 8-10.

Accordingly, Anstadt fails to disclose each and every limitation set forth in claims 1-4, 12, 14, 17-19 and 21-24. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant’s claims 1-4, 12, 14, 17-19 and 21-24 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 12, 14, 17-19

Independent claim 12, as amended, recites a manipulating device that is adapted to contact an organ, and a bag-like device that is adapted to extend around a substantial volume of the organ *and the manipulating device*. The liner 50 in Anstadt does not extend around any manipulating device. In Anstadt, cup-shaped member 30 extends around liner 50. Column 2, lines 28-29; column 5, lines 6-7; FIGS. 4-5. Anstadt does not describe the liner extending around cup 30, or any manipulating device, as recited in independent claim 12. On the contrary, Anstadt describes the opposite: a cup 30 extending around a liner 50.

The limitation of independent claim 12, that a bag-like device is adapted to extend around the manipulating device, is incorporated into claims 14 and 17-19, which depend on claim 12. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant’s claims 12, 14, 17-19 under 35 U.S.C. § 102(b), and withdrawal of these rejections is requested.

Claims 12-17, 21, 23, 24 and 26

In the Office Action, the Examiner rejected claims 12-17, 21, 23, 24 and 26 under 35 U.S.C. § 102(b) as being anticipated by Cox (US 5,150,706). According to the Examiner, Cox teaches an apparatus comprising a manipulating device that is adapted to contact an organ, a bag-like device that is adapted to extend around a substantial volume of the organ and the manipulating device. The Examiner further stated that Cox discloses the bag-like device comprising a pliable net that is formed from a flexible polymer having a center region that engages the manipulating device, and that defines mesh apertures, a perimeter, and includes a drawstring.

According to the Examiner, Cox further teaches a method comprising engaging an organ with a manipulating device, deploying a bag-like device around a substantial volume of the organ, and manipulating the organ with the manipulating device and the bag-like device. The Examiner stated that Cox further discloses securing the bag-like device around the organ and cutting the bag-like device.

Applicant respectfully traverses the rejections to the extent such rejection may be considered applicable to the amended claims. Cox fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claim 12, as amended, recites an apparatus comprising a manipulating device that is adapted to contact an organ. Independent claim 21 recites engaging an organ with a manipulating device and manipulating the organ with the manipulating device. Cox does not disclose a manipulating device, nor does Cox disclose manipulating an organ with any manipulating device.

The Examiner referred to Cox elements 20 and 22 as a manipulating device that is adapted to contact an organ. Cox element 20, however, is a catheter seam, and Cox element 22 is a catheter sleeve. Column 6, line 4. Neither Cox element 20 nor element 22 is a manipulating device, as recited in claims 12 and 21. Rather, catheter seam 20 is nothing more than a gathering of pocket component 12, which the Examiner identified as a “bag-like device.” In other words, catheter seam 20 is a structural feature of, and not a distinct feature from, pocket component 12. This is shown very clearly in Cox FIG. 2.

Moreover, catheter seam 20 is just that, a seam. It is not a “manipulating device” at all. Nowhere does Cox suggest that catheter seam 20 plays any role in manipulating any organ. On the contrary, the function of catheter seam 20 is to create catheter sleeve 22.

Catheter sleeve 22, like catheter seam 20, is a structural feature of, and not a distinct feature from, pocket component 12, as shown in FIG. 2. Catheter sleeve 22, like catheter seam 20, is not a “manipulating device” at all, and does not play any role in manipulating any organ. Rather, the purpose of catheter sleeve 22 is to house a double-lumen catheter 32, 34. The lumens provide infusion, and are not used for organ manipulation.

Furthermore, none of the cited elements is “adapted to contact an organ,” as recited in independent claim 12. None of the cited elements engages an organ or is described as being used to manipulate the organ, as recited in independent claim 21. As shown in FIG. 2, catheter seam 20 and catheter sleeve 22 are on the exterior of pocket component 12, and do not engage or contact the organ. Moreover, because catheter seam 20 and catheter sleeve 22 are on the exterior of pocket component 12, Cox does not describe a bag-like device that is adapted to “extend around ... the manipulating device,” as recited in independent claim 12.

The Examiner pointed out that Cox describes lifting a heart: Column 8, lines 15-16. Cox does not disclose, however, “manipulating the organ with the manipulating device and the bag-like device” as recited in independent claim 21. In fact, Cox does not describe using any structure of the Cox device to lift the heart. Cox certainly does not suggest in any way that catheter seam 20 and catheter sleeve 22 play any part in lifting the heart, or that the catheters in catheter sleeve 22 play any part in lifting the heart. Rather, Cox describes that different catheter segments being used for an entirely different purpose, namely, administration of cold saline. Column 8, lines 18-23.

Applicant submits that not only does Cox not anticipate independent claims 12 and 21, Cox does not even come close to doing so. Cox clearly does not anticipate independent claims 12 and 21. Claims 13-17 include the limitations of independent claim 12. Because Cox does not anticipate claim 12, Cox does not anticipate claims 13-17. Similarly, claims 23, 24 and 26 include the limitations of independent claim 21. Because Cox does not anticipate claim 21, Cox does not anticipate claims 23, 24 and 26.

For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 12-17, 21, 23, 24 and 26 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Allowable Subject Matter

The Examiner stated that claims 5-11 and 25 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, second paragraph, set forth in the Office Action and to include all of the limitations of the base claim and any intervening claims.

The Examiner did not assert 35 U.S.C. § 112, second paragraph, against any of claims 5-11 and 25. Applicant has amended claim 12 to address the Examiner's concerns with claims 12-20 under 35 U.S.C. § 101, and Applicant has amended claim 22 to the Examiner's concern under 35 U.S.C. § 112, second paragraph.

Applicant notes that the Examiner rejected claim 20 under 35 U.S.C. § 101, and did not cite any reference as a basis for rejection of claim 20 under 35 U.S.C. § 102. The Examiner did not specifically list claim 20 as allowable, however. This omission of claim 20 from allowable subject matter appears to have been an oversight. The Examiner specifically stated that the references do not teach or suggest a bag-like device comprising an aperture sized to permit passage of a support shaft and sized to block passage of a manipulating device, which is the subject matter recited in claim 20.

Applicant agrees that claims 5-11 and 25 recite allowable subject matter. For the reasons given above, however, Applicant asserts that claims 5-11 and 25 depend upon allowable independent claims, and consequently claims 5-11 and 25 need not be written in independent form. Applicant believes that all pending claims are allowable.

New Claims

Applicant has added claims 27 and 28 to the pending application. Claims 27 and 28 recite deploying the bag-like device after engaging the manipulating device and the organ. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the invention as claimed in claims 27 and 28.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

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SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

By:

Daniel J. Hanson
Name: Daniel J. Hanson
Reg. No.: 46,757